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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61B 5/04, 5/0488 // A61N 1/36

A1

(11) International Publication Number: **WO 96/10358**

(43) International Publication Date: 11 April 1996 (11.04.96)

(21) International Application Number: PCT/SE95/01120

(22) International Filing Date: 2 October 1995 (02.10.95)

(30) Priority Data:
9403321-4 30 September 1994 (30.09.94) SE
9403344-6 3 October 1994 (03.10.94) SE

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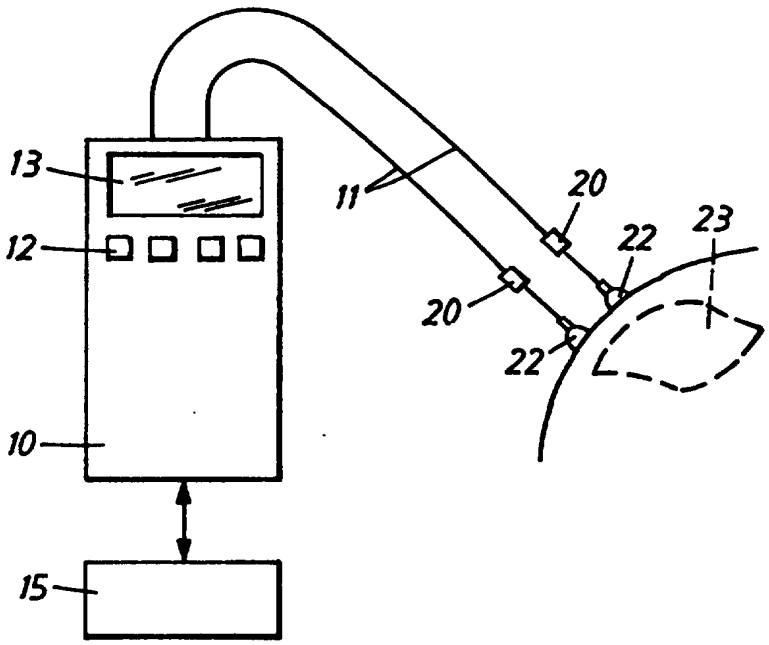
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: METHOD AND DEVICE AT PRIMARILY ELECTROGASTROGRAPHY AND ELECTROUROGRAPHY

(57) Abstract

A method primarily for electrogastography (EGG) of the gastrointestinal tract and electrourography (EUG) of the bladder including measuring of primarily rythmic depolarization signals of primarily gastrointestinal origin and/or vesical origin, electrodes (22) being applied to the patient and signals being detected by means of said electrodes. The method is especially characterized in that said signals, preferably in a filtered condition, are recorded by means of a portable data recording device (10) and are manipulated by means of the device directly mainly online and/or afterwards by means of the device and/or a computer (15) and are correlated to the gastrointestinal or urodynamic or corresponding condition of the patient. The invention also relates to a device for performing the method.



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Method and device at primarily electrogastrography and electrourography

The present invention relates a method for principally electrogastrography (EGG) and electrourography (EUG) comprizing a measuring of principally rythmic depolarization signals of mainly a gastrointestinal origin or a vesical origin.

The invention also relates to a device for performing the method.

Gastric depolarization signals normally occur with a frequency of about three cycles per minut. Other frequencies occur in other other parts. Some, but not all depolarization signals are considered to provoke gastric contractions, but all gastric contractions are considered, as also with EKG, to be preceded by electric depolarization signals. Inadequate depolarization signals might occur and it has proved that anormal signals occur with e.g. stomach suffering, such as indisposition, nervous bladder, incontinence, etc. Moreover, EGG presents thus a new way to achieve gastric motility with the advantage to be a noninvasive method to replace and/or complement other, more known methods, such as ultrasonics, gastric emptying, etc. Ambulatoric EGG can provide an easily usable, noninvasive and inexpensive method to analyse gastric activity e.g. in a domestic environment and can in the medical science facilitate a diagnosis of gastric motility and to prescribe an adequate therapy.

In a corresponding way, EUG is a new method for a noninvasive examination of the urinary bladder. Here below the desciption is concentrated to EGG, but all that may be stated in this respect is generally applicable even to EUG.

The detection of electrical cyclic signals from the stomach, i.e. EGG, was first achieved by Alvarez in 1922. Since then a variety of conditions, such as non explicable indisposition, indisposition during pregnancy, have been describes by mens of EGG.

EGG, however, has so far remained a research instrument adaptable for static and well defined conditions and applications, i.a. due to difficulties to measure feeble skin based EGG–signals in a well defined and unambiguous way.

The present invention provides the possibility for an accurate EGG in such a way that a diagnosis can be achieved with essentially improved

accuracy and stringency, the adaptation to research purposes thus being essentially increased. The improved diagnosis are, as is well known, entailing secondary advantages in form of a reduced convalescence, etc.

The invention thus relates to a method according to the first part of claim 1. The method is especially characterized in what is stated in the characterizing part of said claim.

The invention further relates to a device according to the first part of claim 8. The device is especially characterized in what is stated in the xharacterizing part of said last mentioned claim.

The invention is described in the following in connection to execution examples and the attached drawings, on which

Figure 1 schematically shows the general configuration of a preferred embodiment of a portable system for EGG data recording according to the invention, and

Figure 2 shows a block diagram illustrating the overall logic circuit function of an EGG data recording device acccording to the invention.

In figure 1 the portable EGG and analyzing system comprises a data recording device 10 connected to external lines 11 ending in impedance converting electrodes 20 which then are connected to to skin based readable electrodes 22, preferably to at least two. The recording device is accomplished as a modification of the Digitrapper MkIII for recording pH-data (available from Synectics Medical Inc., Irving, Texas). A set of four keys 12 are adapted to control the data recording device and to let the patient register periodical data for events during recording. A display 13 cooperates to service the device 10 by (1) showing a menue driven control system during the preparation and the analys of the recording and (2) showing the recorded data on line during recording.

The impedance converting electrodes 20 comprize a field effect transistor circuit operating as an impedance converter with an amplifying factor 1. The electrodes 20 are connected to surface electrodes 22 placed on top of the patients stomach 23, small intestine, bladder, etc. The EGG or EUG signals are recorded and sent through said impedance converting

electrodes 20 and further through said lines 11 to the data recording device 10.

When the EGG or EUG recording operations are completed, data are sent from the device 10 into a computer 15, e.g. a PC, to analyze the recorded gastric signals as to the gastric function and generates a report of analysis (not shown). Alternatively, the device 10 may comprise a computer for a corresponding handling of said data.

In the report of analysis the relation between the postprandial and preprandial variables are presented, as well as the variable distribution and the values for bradygastria, normal frequency, tachygastria and duodenal gastric activity. Frequency diagrams are shown for the various periods. The present program of analysis, the software, shows the spectrum of variables from e.g. three prepandial periods and three postprandial periods. Moreover, the deviation from the fasting EGG activity is presented during the born condition as a relation of the postprandial/preprandial variables, as stated previously.

The standard report shows a spectrum of variables calculated by means of a fast frequency conversion, FFT, of the EGG signals from e.g. three preprandial periods and three selected postprandial periods. The recording device is sampling EGG data with a sampling freequency of about 2Hz during recording. These data are used and each line of the spectrum of variables uses 512 samplings during each cycle of four minutes. The X-axis shows the cycles per minut and the Y-axis the variable. The Z-axis shows the time intervals.

The next line of four minutes is using both the samplings from the previous line and new samplings and overlaps the previous line by 75 percent and the second line thus differs from the first one by one minute. Thereafter, a third line is achieved in the same way etc. until a complete period of interest may be presented.

Moreover, the distribution of variables between bradygastria, normally three per minute, tachygastria and duodenal respiration patterns are presented for each period of interest.

Thus, it is i.a. possible to decide, if the pattern for a depolarization is normal or anormal, as with gastric paresis, indisposition of post operation patients, etc.

Various periods of interest can be illustrated compared with a so-called normal period (basic period for the same patient) so that the patient in practice is used as his own standard level. The difference in the EGG pattern and the gastric activity between normal and anormal periods, with prokinetic medicine, between preprandial and postprandial periods (with a more regular pattern to probably occur during the post-prandial period) can thus be identified. Such differences between periods of gastric activity are then devided into columns of bradygastria, normal three per minut frequency, tachygastria and duodenal respiration.

The data recording system is adapted so, that retractable kolyt electrodes with low polarization 22 are recording the EGG signals with 20 to 100 microvolt and transfer said signals to an impedance converter 20 with an amplifying factor 1.

The signals are then sent to the data recording device 10 via an eight pin phone adapter 60, figure 2. Moreover, the signals are according to figure 2, after an analogue amplifying step with an optimal automatic offset 61 and an amplifying portion regulator 62, sent to an anologue/digital converter in the microprocessor unit 63.

The sampling speed is set by the operative system (OS) and is controlled by means of a real time clock 64.

A RAM 65 is used to save data.

The OS is programmed in a PROM 66. An ASIC-circuit is used for address decoding.

The display 68 has 2 x 16 alfanumeric characters for recording the menue and the periodical values.

The keyboard 69 is a board with four keys to control any menue events and patients events and for an automatic ON/OFF control.

A contact 70 with 15 pins is the output channel to a computer or a printer 71.

The voltage control unit 72 is supplied by a 9 volt standard alkali battery. As a part of this unit a chargeable litium battery is provided as a backup for the RAM 65 and the clock 64.

A control circuit 73 takes care of any eventual absence of current by means of a NMI 74 and is also part of the current dsitribution system.

The microprocessor unit 63 has six inputs with item 74 being analogue inputs, 76 and 77 are used for data and addresses, 78 and 79 are used for parallel communication and 80 is used for serial communication.

Besides EGG based gastointestinal measurements also complementary measurements/researches can be performed according to the invention to achieve improved diagnostic possibilities and a more reliable diagnosis.

Thus, the EGG measurements are supplemented with impedance measurements with a larger or smaller number of sensors of a convenient type applied to the skin at interesting measuring spots, i.a. in connection to the EGG electrodes.

Moreover, gastric ultrasonis studies can be performed as a supplement, contractions and stomach emptying and bladder emptying possibly be detected by means of ultrasonics, the results being correlated with the EGG or EUG measurements.

The measuring of high frequency vibrations according to GB-2,211,094 might also be performed as a supplement to the EGG measurements, any sound then being analyzed.

Moreover, measurements related to electric impedance tomography according to a method patented to Yvonne Magnall can be combined with EGG measurements.

The method according to the invention as well as its operation should be essentially evident from what is stated previously.

According to the invention, a preferably portable or ambulatoric recording device for i.a. EGG data with an analysing system for said data can thus be used, a real time analysis then possibly being performed and presented to the device or dealt with afterwards by means of a computer and presented on the screen or by printed matter.

Preferably special detachable skin based carbon electrodes with a low depolarization and a high stability are placed over the patient antrum and/or other places. One of the electrodes is connected directly to an impedance converter, a field effect transistor circuit, which in combination with a reference line from another electrode is connected to a digital EGG recording device (EGG Digitrapper). This latter collects EGG

sampling values from the patient antrum or corrsponding part, e.g. four times each second and stores the mean value each second in a digital memory. The patient can store events such as meals, etc. The stored values can be electrically transmitted to the examiner or in form of the device 10 and an analysis might be performed after a transmission to a computer or by means of the analysis system in the device. The invention also includes a special auto–offset and an automatic amplifying control to standardize the EGG signals from the patients with various stomach wall ticknesses, skin resistance, non identical electrode positions, etc. In the case the EGG measurements are combined with further measurements the results of these measurements are aslo recorded by means of the device, Digitrapper, and are used as a basis for a total analysis.

The analysing system according to the invention comprising programs, the soft ware, is adapted to interpret the recorded signals in a filtered form and relate these to i.a. gastric performance. The system for an EGG analysis is preferably based on the Multigram Version 5.10 for motility procedures from Gastrosoft Inc., Irving, Texas, this version being essentially changed to analyse the EGG and to report the EGG function in such a form as to be clinically and scientifically usable.

The main menue of the system cocmprises in one embodiment six choices: Patient Records, Read Digitrapper, Review Procedure, Print Report, System Constants and Quit.

When a data recording device with gastric EGG signals has to be charged with the system software the choice *Read Digitrapper* is chosen and the patient data is filling the screen, according to appendix 1.

In the next step the system software is instructing the user to connect the Digitrapper to the computer with an interface cable and to place the Digitrapper in a communication mode. When this is performed, data are charged and stored automatically in a patient file on the computer hard disk.

However, if instead an already charged patient file will be the file of interest the user selects the choice *Patient Record* from the main menue and an already stored patient file is selected.

When a patient file first is stored in the computer via the choice

Patient Record or *Read Digitrapper* said raw EGG data can be overhawled and organized with the choice *Review Procedure.* In *Review Procedure* it is possible to modify certain periods as indicated by the patient when using one of the *Patient Event* keys 12 in the Digitrapper 10 during recording. New periods of interest can also be indicated, i.e. certain periods being regarded as normal for the patient and with which other periods (such as pain periods) might be compared. In this way the patient is acting as his own standard in the respect that deviations in the EGG activity can be analysed from said normal and anormal periods. Other periods to be compared in a similar way are preprandial and postprandial periods and a medium nightly activity with an early morning activity. When the user first has determined any periods of interest he might leave the choice *Review* by using the ESC key being always used for a backstaging in the main menue and to recreate the main menue screen.

Thereafter, the user can print a standard analysis report by using the choice *Print Report.* Said report can be achieved by the choice *System Constants* to be described here below.

When selecting *System Constants* in the main menue it is possible to select any of the choices *Design Procedure, Design Diary, Set Environment, Set Printer Parameters* and *Back to Main Menue. Design Procedure* provides the user with a screen with analysis periods to be selected in accordance with appendix 2.

The procedure can be formed further on the next screen which appears when pressing the *Page Down* key.

Definitions for bradygastria and tachygastria and other conditions as well as selecting the software filter and amplifying factors can be achieved on the screen according to appendix 3.

Selecting *Design Diary* shown in appendix 4 provides the user with the possibility to arrange the study in preselected periods.

Selecting *Set Environment* permits the user to adapt the Path to the patient data file to specify the type of monitor to be used and to specify, if the scanned data are to be used and if a light signal should be on (to indicate to the user, that the connection between the Digitrapper and the computer during charging is not correct).

Selecting *Set Printer Parameter* is shown in appendix 5 and let the user select a printer and configurate the size and the position of the written report.

Selecting *Back to Main Menue* carries the user back to the main menue and selecting *Quit* in the main menue ends the programme.

As evident from above the invention provides essential advantages and new possibilities in comparison with what is known in the art. Thus the invention provides improved diagnostic possibilities, an examination in the home, etc.

By means of the portable device said signals can thus be recorded in real time for a real time detection of a postsurgical or equivalent start of gastric activity.

According to another application said signals are recorded noninvasively or invasively and are correlated with an induced activity by means of a gastrointestinal pace maker, a desired pace maker influence then being adjusted on the base of a feedback information in form of said signals in the condition preferably achieved by means of said apparatus.

The measuring with a refined technique according to the invention provides the possibility of a noninvasive detection of gastric stops and a phase detection.

The invention has been described above in connection with execution examples and preferred embodiments. Various embodiments and minor changes can of course be envisaged without leaving the original spirit of the invention.

The data recording device 10 might thus in special applications be stationary or semistationary and not necessarily be portable or ambulatoric. The main application of the invention is however related to portable or ambulatory variations and its weight is preferably less than about 2 kg.

As should be evident from the preceding description the application of the method and the device according to the invention is not limited to the stomach, but other parts of the gastrointestinal part as well as the bladder, etc. can become the object for measurements etc. according to the invention.

As already mentioned the patient wall impedance might be recorded this being achieved by recording electric signals related to said wall impedance, said signals providing the basis for a calibration/standardization of the recorded gastric or corresponding depolarisation signals, preferably of the amplitude.

For the determination in real time of a gastric start during postsurgical conditions or corresponding the analysis system is conveninetly adapted to decide by means of a comparison with data for gastric activity, if it has started and exists to such an extent that nourishment may be administered to the patient. The result of a nourishment administration can in a corresponding way be decided under a corresponding or a similar condition.

CLAIMS

1. A method primarily for electrogastrography (EGG) of the gastrointestinal tract and electrourography (EUG) of the bladder including measuring or primarily rythmic depolarization signals of primarily gastrointestinal origin and/or vesical origin, electrodes being applied to the patient and signals being detected by means of said electrodes, **characterized in that** said signals, preferably in a filtered condition, are recorded by means of a portable data recording device and are manipulated by means of the device directly mainly online and/or afterwards by means of the device and/or a computer and are correlated to the gastrointestinal or urodynamic or corresponding condition of the patient.

2. A method according to claim 1, **characterized in that** the characteristics of the recorded signals are related to the patients condition, such as symptoms, uresis of a controlled or an uncontrolled type, postprandial and preprandial conditions or events, etc, the patient in relevant cases himself providing the device with data of said conditions or events, etc.

3. A method according to claim 1 or 2, **characterized in that** said signals are treated and presented as one or several of the following variables:

a) the relation between postprandial and preprandial variables,
b) the distribution of variables,
c) bradygastric values,
d) tachygastric values,
e) values of duodengastric activity,
g) the relation between symptomatic and nonsymptomatic periods related to the gastrointestinal tract and the bladder,
h) vesical values before, during and after uresis.

4. A method according to claim 1, 2 or 3, **characterized in that** the recording of said signals is combined with any or several further measurements in the group of

a) noninvasive measurements of the impedance, one or several pairs of skin based sensors being applied, by means of which said detected signals are sent to said device,
b) ultrasonic measurements for detecting emptying and contrations,
c) measurements of high frequency surface vibrations according to GB2,211,094 of both the stomach and the bladder,
d) electrical impedance tomography,
e) stomach emptying with a gamma camera,
f) measurements of the pressure in the gastrointestinal tract, the bladder or the uretrea,
g)measurements by means of a laser and doppler effects.

5. A method according to claim 1, 2, 3 or 4, **characterized in that** said signals are recorded in real time for a real time analysis during an intensive care, a postsurgical, surgical or other diagnostic measuring of the gastrointestinal or bladder activity.

6. A method according to claim 1, 2, 3, 4 or 5, **characterized in that** said signals are recorded noninvasively or invasively and are correlated to an activity induced by a gastrointestinal or bladder pacemaker, the pacemaker effect being adjusted on the basis of a feedback information in form of said signals in a condition preferably treated by means of said apparatus.

7. A method according to claim 1, 2, 3, 4, 5 or 6, **characterized in that** electrical signals correlated to the patient wall impedance are recorded and are used as a basis for a calibration/standardization of the recorded gastric depolarization signals or bladder depolarizations signals, preferably of the amplitude.

8. A device primarily for electrogastrography (EGG) of the gastrointestinal tract and electrourography (EUG) of the bladder including measuring or primarily rythmic depolarization signals of primarily gastrointestinal origin and/or vesical origin, including electrodes to be applied to the patient and to detect said signals, **characterized in that** a preferably portable data recording device (10) is adapted for recording said signals, preferably in a filtered condition, said signals being adapted to be treated by means of said device mainly online and/or afterwards by

means of said device and/or a computer to be correlated to the gastrointestinal or vesical or a corresponding condition of the patient.

9. A device according to claim 1, said measurements being preferably noninvasive, **characterized in**

a) at least two circuit electrodes for impedance converter field effect transistors,

b) two skin based electrodes with a low polarization, each being applied to each such an impedance converting electrode,

c) a portable and in adaptable cases ambulatory data recording device,

d) electricity conducting devices as a connection between each such an impedance converting electrode and said data recording device.

10. A device according to claim 8 or 9, **characterized in** devices for measuring the abdominal wall impedance of patients and to generate electric signals correlated to said impedance and electricity conducting devices as a connection between the devices for measuring the wall impedance and said data recording device.

11. A device according to claim 10, **characterized in that** devices are provided for treating such impedance signals to select an amplification factor for an automatic control of the gain and the offset of such gastric depolarization signals to achieve a standard amplitude for such gastric depolarization signals.

12. A device according to claim 9, 10 or 11, **characterized in**

a) a number of amplifiers and a number of filters for such gastointestinal signals and vesical signals,

b) a keyboard enabling the generating registeration of patient related event signals of the patient,

c) a digital display.

13. A device according to claim 9, 10, 11 or 12, **characterized in that** the data recording device is adapted to receive signals from complementary measurements adapted to be combined with said depolarization signals to evaluate the gastrointestinal condition and/or the vesical condition of the patient, such as indisposition, gastroparesis, gastrointestinal obstruction, stomach emptying speed, incontinence, nervous bladder, neuropathy, etc.

Fig. 1

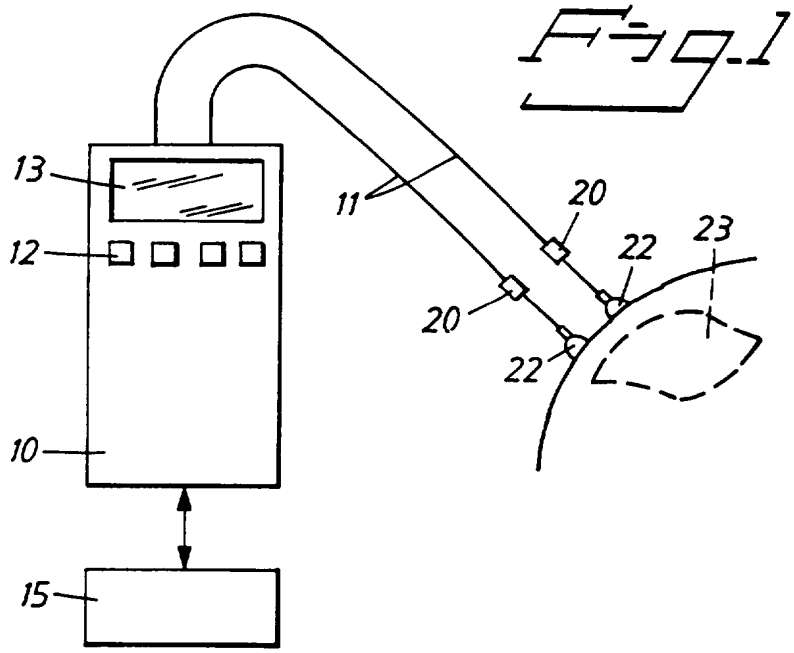
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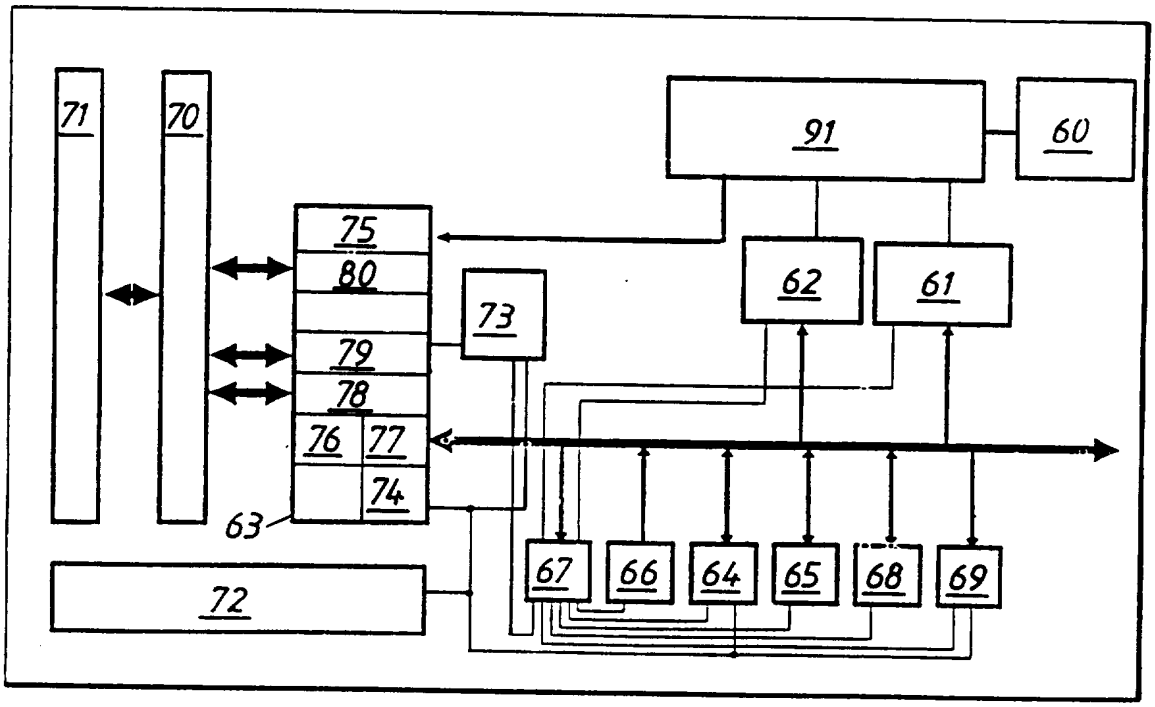
Fig. 2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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01120

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/04, A61B 5/0488 // A 61 N 1/36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	Database Chinese Patent Abstracts in English on Dialog, week 9533, INPADOC, (Vienna, Austria), No. 4049378, CN 1079379 A (HEFEI DIVISION CHINESE ACADEMY), abstract	1,3,5,8
Y	--	2,7,10-13
X	CN 1079379 A (HEFEI DIVISION CHINESE ACADEMY), 15 December 1993 (15.12.93), figures 6,15	1,3,5,8,9
Y	--	2,7,10-13

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 January 1996	27 -01- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Malin Keijser Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01120

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

05/01/96

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